

**APPENDIX A: 510(k) SUMMARY**

**Sponsor/Submitter:** Acclarent, Inc.  
1525-B O'Brien Drive  
Menlo Park, California 94025

**Contact Person:** Courtney Kalof  
Regulatory Affairs Coordinator  
Phone: (650) 687-4473  
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**Date of Submission:** November 16, 2009

**Device Trade Name:** Relieva Stratus MicroFlow Spacer

**Common Name:** MicroFlow Spacer

**Device Classification:** Class I

**Regulation Number:** 21 CFR 878.4800

**Classification Name:** Manual surgical instrument for general use

**Product Code:** KAM

**Predicate Device:** Relieva Stratus MicroFlow Spacer (K083574)

**Device Description:** The MicroFlow Spacer is a device that maintains an opening at the target sinus for up to 14 days postoperatively. There are two models of the MicroFlow Spacer: Ethmoid and Frontal. The modified device can be manually removed during an office follow-up visit at any time.

**Indications for Use:** The MicroFlow Spacer (Ethmoid) is indicated for use as a postoperative spacer to maintain an opening to the ethmoid sinuses within the first 14 days following surgery. The MicroFlow Spacer also helps to prevent obstruction.

The MicroFlow Spacer (Frontal) is indicated for use as a postoperative spacer to maintain an opening to the frontal sinuses within the first 14 days following surgery. The MicroFlow Spacer also helps to prevent obstruction.

**Technological Characteristics:** The MicroFlow Spacer is designed to be implanted into the frontal or ethmoid sinuses and to maintain its position by a self-retention mechanism.



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**Performance Data:**

The MicroFlow Spacer met all performance acceptance criteria.

**Summary of Substantial  
Equivalence:**

The MicroFlow Spacer is substantially equivalent to the predicate device as confirmed through relevant performance tests.



DEPARTMENT OF HEALTH & HUMAN SERVICES

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MAR 3 2010

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Mail Center - WO66-G609  
Silver Spring, MD 20993-0002

Acclarent, Inc.  
c/o Ms. Courtney Kalof  
Regulatory Affairs Coordinator  
1525-B O'Brien Dr.  
Meno Park, CA 94025

Re: K093594

Trade/Device Name: Relieva Stratus MicroFlow Spacer  
Regulation Number: 21 CFR 878.4800  
Regulation Name: Manual surgical instrument for general use  
Regulatory Class: Class I  
Product Code: KAM  
Dated: January 26, 2010  
Received: January 27, 2010

Dear Ms. Kalof:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Malvina B. Eydelman, M.D.  
Director  
Division of Ophthalmic, Neurological,  
and Ear, Nose and Throat Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure



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**APPENDIX B: INDICATIONS FOR USE STATEMENT**510(k) Number (if known): K093594

Trade Name: Relieva Stratus MicroFlow Spacer

Common Name: MicroFlow Spacer

Indications For Use: The MicroFlow Spacer (Frontal) is indicated for use as a postoperative spacer to maintain an opening to the frontal sinuses within the first 14 days following surgery. The MicroFlow Spacer also helps to prevent obstruction.

The MicroFlow Spacer (Ethmoid) is indicated for use as a postoperative spacer to maintain an opening to the ethmoid sinuses within the first 14 days following surgery. The MicroFlow Spacer also helps to prevent obstruction.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF  
NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel C. Cline  
(Division Sign-Off)

Division of Ophthalmic, Neurological and Ear,  
Nose and Throat Devices

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